

### **DETAILED ACTION**

Claims 1, 8, 11-13 are pending and under consideration. Applicant's arguments filed 05/02/2011 have been fully considered. The amendment dated 05/02/2011 has been entered. Claims 2-7, 9-10 and 14-35 are canceled.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Claim is depended from canceled claim 10. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 8, 11-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the claim 1 amendment dated 05/02/2011, by the recitation, wherein the CEA protein is a human CEA protein as set forth in SEQ ID NO: 20, wherein the fusion protein is capable of producing an immune response in a mammal.

#### ***Response to Arguments***

Applicants argue as stated above, claim 1 is amended herein to indicate that the CEA protein is a human CEA protein as set forth in SEQ ID NO:20, wherein amino acids 679-702 of SEQ ID NO:20 are deleted. Applicants assert that, as amended, the claim refers to a single CEA protein variant in which the entire portion from amino acid 679 through amino acid 702 is deleted. As such, Applicants respectfully assert that claim 1, and dependent claims 8 and 11-13 are in compliance with the written description requirement. Applicant's arguments have been fully considered and are persuasive. A new ground of rejection is detailed below.

***Claim Rejections - 35 USC § 112/New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims **1, 8, 11-13** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment dated 05/02/2011.

Claims 1, 8, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim **1** of the present invention has been amended to recite and encompass a nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a subunit B of heat labile enterotoxin of E. coli (LTB); wherein the CEA protein is a human CEA protein as set forth in SEQ ID NO:20 wherein amino acids 679-702 of SEQ ID NO :20 are deleted; and wherein the fusion protein is capable of producing an immune response in a mammal. Claim **8**, is directed to the nucleic acid molecule of claim 1 wherein the LTB is truncated of its signal sequence. Claim **11** is directed to the nucleic acid molecule of claim 1, wherein the sequence of nucleotides comprises a sequence of nucleotides as set forth in SEQ ID NO:9, SEQ ID NO:11, or SEQ ID NO:12. Claim **12** is directed to the nucleic acid molecule of claim 1, wherein the sequence of nucleotides is as set forth in SEQ ID NO: 12. Claim **13** is directed to the nucleic acid molecule of claim 8, wherein the C-terminal end of the CEA protein is fused to the N-

terminal end of LTB.

Literal support for SEQ ID NO: 20, wherein amino acids 679-702 of SEQ ID NO: 20 are deleted as required in claim 1 in combination with sequences of nucleotides as set forth in SEQ ID NO: 9. or SEQ ID NO: 11, or SEQ ID NO: 12 capable of producing an immune response in a mammal cannot be found in the specification. More specifically the present invention describes biologically active fragments or mutants of SEQ ID NOs: 7, 9, 11, 12, 14, 21, 25, 49, 50, and 52, which encode mRNA expressing exemplary CEA fusion proteins [0094]. Any such biologically active fragment and/or mutant will encode either a protein or protein fragment which at least substantially mimics the pharmacological properties of the hCEA protein, including but not limited to the hCEA protein as set forth in SEQ ID NO:20 [0094]. Any such polynucleotide includes but is not necessarily limited to: nucleotide substitutions, deletions, additions, amino-terminal truncations and carboxy-terminal truncations. The mutations of the present invention encode mRNA molecules that express a functional CEA fusion protein in a eukaryotic cell so as to be useful in cancer vaccine development [0094], can be found in the specification or in the sequence listing. Upon further review of the instant specification the examiner could not find support for SEQ ID NO: 20, wherein amino acids 679-702 of SEQ ID NO: 20 are deleted as required in claim 1 in combination with sequences of nucleotides as set forth in SEQ ID NO: 9. or SEQ ID NO: 11, or SEQ ID NO: 12 capable of producing an immune response in a mammal by way of the claimed nucleic acid molecule composition. It is noted that the Applicants fail to point out any specific support for the present claim amendments.

MPEP 2163.06 notes "If new subject matter is added to the disclosure, whether it be in the abstract, the specification, or the drawings, the examiner should object to the introduction of new matter under 35 U.S.C. 132 or 251 as appropriate, and require applicant to cancel the new matter. If new matter is added to the claims, the examiner should reject the claims under 35

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U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). The examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant. In an instance in which the claims have not been amended, per se, but the specification has been amended to add new matter, a rejection of the claims under 35 U.S.C. 112, first paragraph should be made whenever any of the claim limitations are affected by the added material. When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

To the extent that the claimed composition is not described in the instant disclosure, claims 1, 8, 11-13 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case, the claims as amended require SEQ ID NO:20, wherein amino acids 679-702 of SEQ ID NO :20 are deleted as required in claim 1 in combination with sequences of nucleotides as set forth in SEQ ID NO : 9. or SEQ ID NO: 11, or SEQ ID NO: 12 capable of producing an immune response in a mammal merely citing "SEQ ID NO:20, wherein amino acids 679-702 of SEQ ID NO :20 are deleted as required in claim 1 and in claim 11 the nucleic acid molecule of claim 1, wherein the sequence of nucleotides comprises a sequence of nucleotides as set forth in SEQ ID NO:9, SEQ ID NO:11, or SEQ ID NO:12." an artisan of skill in the art would require undue experimentation to practice or make and/or use the claimed invention.

***Conclusion***

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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